UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: RANBAXY GENERIC DRUG APPLICATION ANTITRUST LITIGATION

MDL No. 2878

THIS DOCUMENT RELATES TO:

All Cases

Master File No. 19-md-02878-NMG

<u>DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR</u> MOTION TO AMEND CASE MANAGEMENT ORDER NO. 4

Pursuant to Magistrate Judge Kelley's December 9, 2020 Order (ECF No. 305), Defendants Ranbaxy Inc. and Sun Pharmaceutical Industries Ltd. ("Defendants"), now move for an extension of approximately three weeks to the deadline for Defendants to serve responsive expert reports, until February 15, 2021, and adjustments to all existing case deadlines consistent with the same as set forth in the attached Exhibit A.

BACKGROUND

On September 23, 2020, Defendants filed a motion to compel non-party AstraZeneca Pharmaceuticals L.P. ("AstraZeneca") to produce AstraZeneca's transaction-level sales data, including information on discounts, returns, rebates, and chargebacks. Ranbaxy first requested this data in a July 23, 2019 subpoena, but despite nearly a year of negotiations AstraZeneca refused to produce it. (*See* Defs.' Mot. to Compel, Doc. Nos. 256, 257; Jackson Decl. Doc. No. 258.) In response to Defendants' motion, AstraZeneca argued that it would be unduly burdensome to produce the requested data. (*See* AstraZeneca Opp'n., Doc. No. 267.)

This Court referred Defendants' motion to Magistrate Judge Kelley (Doc. Nos. 259, 262), who heard argument on October 7, 2020. (Doc. No. 270.) After the hearing, Defendants continued to confer with AstraZeneca in response to Magistrate Judge Kelley's direction to see whether "Ranbaxy can narrow its request" and to discuss potential cost-sharing in light of AstraZeneca's claim that it would be burdensome to produce the requested data. (Doc. No. 270.) Defendants and AstraZeneca conferred on several occasions and submitted four separate status reports to the Court regarding the outcome of those discussions. (Doc. Nos. 271, 273, 278, 293.)

After productive negotiations, the only categories of data that remained in dispute were (1) administrative fees paid to certain purchasers of Nexium and (2) Medicaid rebates, which categories AstraZeneca had only confirmed the existence of in early November. (Joint Status Rep., Doc. No. 293.) On November 12, 2020, the Court heard argument on the remaining areas of dispute, including AstraZeneca's argument that the requested data was not relevant. (Doc. No. 298; see also Mot. for Reconsideration at 7, Doc. No. 300). At the conclusion of that hearing, and after determining that the requested data was relevant, the Court ordered AstraZeneca to produce the two aforementioned categories of data by December 10, 2020. (Doc. No. 298.) AstraZeneca subsequently filed a motion for reconsideration on November 30, 2020, claiming that it could not "practicably comply with the Court's order to produce Medicaid rebate data" by December 10 and could not feasibly complete its production of Medicaid rebate data prior to January 15, 2021. (Mot. for Reconsideration at 5, Doc. No. 300.) Defendants opposed AstraZeneca's motion, explaining that their motion had been pending for more than two months and with their expert report deadlines fast approaching, the data needed to be produced no later than December 17, 2020, a month in advance of Defendants' deadline. (Defs.' Opp'n at 3-4, 9, Doc. No. 304.)

In response to AstraZeneca's request, Magistrate Judge Kelley ordered AstraZeneca to produce the data by January 15, 2021. (Doc. No. 305.) As Defendants indicated in their submission opposing the motion for reconsideration (Doc. No. 304), and during the hearing on the same, Defendants need thirty days from the date of production for their experts to complete the required analyses of the data and incorporate them into their expert reports. Magistrate Judge Kelly directed Defendants to file a motion to this Court requesting a 30-day extension of the deadline to submit expert reports relating to market power and market definition and to confer with Plaintiffs regarding the same. (ECF No. 305.)

On December 10, 2020, Defendants proposed two potential schedules to Plaintiffs: (1) that extended Defendants' deadline to submit responsive expert reports relating to market power and market definition until February 15, 2021, did not change any deadlines related to other expert reports, and extended all other deadlines by approximately three weeks (including the deadline for Plaintiffs' rebuttal expert reports relating to market definition and market power); and (2) a schedule that extended Defendants' time to submit its expert reports until February 15, 2021, but kept all other deadlines, including the trial date, the same.

Plaintiffs responded on December 14, 2020, proposing a two-week extension for all of Defendants' expert reports. Specifically, Plaintiffs proposed the submission of Defendants' responsive expert reports by February 4, 2021; Plaintiffs' rebuttal expert reports by March 29, 2021; and the completion of expert depositions by April 23, 2021. Plaintiffs explained that any extension of time to submit expert reports relating to market power and market definition should apply to all expert reports because they believed there was overlap between the market reports and their other expert reports. Plaintiffs would not agree to any extension of time that impacted the existing trial dates and Rule 26(a)(3) pretrial exchanges. Defendants informed Plaintiffs that they

were amenable to aligning the deadlines for all expert reports, but that 30 days was the minimum amount of time needed to incorporate the analyses into their reports, which would necessarily require an adjustment of trial and pretrial deadlines. As the parties have been unable to reach an agreement, Defendants now submit this motion to extend all remaining case deadlines by approximately three weeks (i.e., 30 days from the date of AstraZeneca's production) to allow Defendants adequate time to analyze and incorporate AstraZeneca's rebate data into their expert reports.

ARGUMENT

The Medicaid rebate data that AstraZeneca will produce on January 15, 2021 will provide important information on the net price received by AstraZeneca for its Nexium products. This is particularly critical to Defendants' defenses of the case in light of the market definition and market power report submitted by Plaintiffs' expert, Dr. Thomas McGuire, in which he opines that AstraZeneca had monopoly power with respect to Nexium prior to generic entry and that this monopoly power is evidence that Defendants had market power over the generic equivalent. Because the net price represents the actual per-unit amount the manufacturer receives for the sale of a product, it is essential to assessing market power and market definition. All rebate data, including the Medicaid rebate data, are necessary to accurately calculate the net price received by AstraZeneca for the sale of Nexium during the relevant period.

As Defendants explained during the December 9, 2020 hearing, Defendants will need at least 30 days to assess AstraZeneca's rebate data and to incorporate those analyses into their responsive expert reports. Medicaid rebate data are complex, as is the process of reconciling the Medicaid rebate data with the other elements of AstraZeneca's transactional data, analyzing the

dates, and using the data to prepare analyses that respond directly to some of the analyses presented by Dr. McGuire.

Defendants made every effort over the last year to obtain this important data, however, as shown by both Defendants' and EPPs' motions to compel (EPP Emergency Mot. to Compel, Doc. Nos. 260, 261), AstraZeneca was unfortunately unwilling to comply with their subpoena obligations without the Court's intervention. Because the Court has now provided AstraZeneca until January 15, 2021, to complete its production, Defendants respectfully request an adjustment that will afford them adequate time to analyze AstraZeneca's data and incorporate it into their expert reports. The two-week extension proposed by Plaintiffs will not give Defendants enough time to complete these analyses. Indeed, when Plaintiffs filed their own motion to compel certain rebate data from AstraZeneca, they also requested that AstraZeneca complete its production three weeks prior to the deadline for their reports. (See EPP Mot. at 3 (noting that given expert reports were due October 29, 2020, "EPPs' expert has advised that the latest date that data would be received and still be utilized by EPPs is October 9, 2020."))

Finally, should the Court grant Defendants' motion to submit their expert reports by February 15, 2021, Defendants respectfully request that all other case deadlines are extended by the same approximately three-week period. Although Plaintiffs have proposed extending the deadlines for summary judgment briefing and keeping the trial date, this would provide for summary judgment briefing to be completed only three business days before the August 4, 2020 hearing on those motions. It would also require the parties to begin exchanging Rule 26(a)(3) disclosures only ten weeks after that briefing was completed, also reducing the amount of time available to the Court to decide motions for summary judgment before the start of trial. Defendants see no reason to unnecessarily reduce the time for the parties and the Court to prepare for a trial of

this magnitude, and request that the Court approve the schedule set forth in the attached Exhibit A.

CONCLUSION

Defendants respectfully request that the Court grant Defendants' Motion to Amend Case Management Order No. 4 to permit Defendants to serve their responsive export reports by February 15, 2021, and to extend all other deadlines as set forth in Defendants' Exhibit A.

Dated: December 14, 2020

/s/ Devora W. Allon

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CERTIFICATE OF SERVICE

I, Devora W. Allon, hereby certify that this document was electronically filed with the

Clerk of the Court for the District of Massachusetts by using the CM/ECF System, which will

provide notification of such filing on all registered CM/ECF users on this 14th day of December

2020.

Dated: December 14, 2020

/s/ Devora W. Allon

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